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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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5487	7590	08/10/2007	EXAMINER	
ANDREA Q. RYAN			BOESEN, AGNIESZKA	
SANOFI-AVENTIS U.S. LLC				
1041 ROUTE 202-206			ART UNIT	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/018,273	Applicant(s) PERRICAUDET ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15 and 17-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Amendment filed May 21, 2007 in response to the Office Action of November 22, 2006 is acknowledged and has been entered. Claim 1 has been amended. Claims 1-7, 7-11, 13-15, and 17-32 are under examination.

Claim Rejections - 35 USC § 112

Rejection of claims 1-5, 7-11, 13-15, and 17-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of Applicants' amendment.

Rejection of claims 1-5, 7-11, 13-15, and 17-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in view of Applicants' amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Rejection of claims 1-5, 7-9, 11, 13, 19, 22, 24, 26, 28, 30, and 31 under 35 U.S.C. 102(a) as being anticipated by Cho et al. (Gene Therapy, May 2000, Vol. 7, p. 740-749, Abstract in IDS of 6/30/2003) is **maintained**. Applicants state that the English copy of the priority document will be filed upon its receipt.

Because the English copy of the foreign priority document has not been provided, the current claims are given priority to PCT/FR00/01594. English copy of the priority document would help overcome this rejection.

Claims are drawn to a defective adenovirus comprising at least one DNA sequence encoding the specific human iodine transporter (Na⁺/I) NIS, wherein DNA sequence is placed under the control of CMV promoter. The adenovirus is a human adenovirus type Ad2 or Ad5. The recombinant adenovirus comprises deletions of all or part of an E1 region.

Cho et al. disclose expression of human iodine transporter (Na⁺/I) NIS in replication-deficient/defective recombinant adenovirus Ad5 under control of CMV promoter (see the entire document, particularly Materials and Methods and Results). The recombinant adenovirus disclosed by Cho et al., comprises deletions in E1 region (see Materials and Methods and Figure 1). Thus by this disclosure Cho et al. anticipate the current claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1-5, 7-9, 11, 13, 15, 17-19, 21, 22, 24, 26, 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandell et al. (Cancer Research, February 1999, Vol. 59, p. 661-668, IDS of 12/7/2001) in view of Wilson et al. (US Patent 5,652,224) is **maintained**.

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Mandell and Wilson references cannot be properly combined because "Wilson teaches a virus whose active component is an RNA molecule, whereas the vector of Wilson requires DNA. Accordingly there is no expectation of success from combining the disparate molecular structures." Applicants further argue that "the means of combination are not believed to be enabled in part because an adequate written description of the final construct and the methods for making the same are not provided." In response to Applicants' arguments, it is not clear if Applicants intended to refer to one and the same reference (by Wilson) or two different references. It is however noted that both Mandell's and Wilson's viral vectors are comprised of DNA (see Materials and Methods of Mandell and Abstract and Examples of Wilson). Both Mandell's and Wilson's heterologous genes comprised within their viral vectors are DNA molecules. It is the Office's position that both references by Mandell's and Wilson's provide an enabling disclosure evidenced by working examples and methods describing the construction of recombinant viruses by both references. Thus it is the Office's position that the combined teaching of the cited references is enabled. One would have had a reasonable expectation of success to make a construct of adenoviral vector and Mandell's human iodine transporter (Na⁺/I⁻) NIS because the recombinant technology has been known at the time the current invention was made as evidenced by Wilson.

Thus because the combination of references by Mandell and Wilson renders the present invention obvious, as discussed on the record in the Office action of November 22, 2007, the rejection is maintained.

Rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Mandell et al. (Cancer Research, February 1999, Vol. 59, p. 661-668, IDS of 12/7/2001) in view of Wilson et al. (US Patent 5,652,224) as applied to claims 1-5, and 7-9 and further in view of Sauvage (US Patent 6,022,708) **is maintained.**

Applicants argue that claim 10 is patentable over the applied art in view of the arguments presented with respect to the rejection of claim 1 above. As discussed above, Applicants' arguments are not persuasive and therefore the rejection is maintained.

Rejection of claims 14, 20, 23, 25, 27, 29 and 32 under 35 U.S.C. 103(a) as being unpatentable over Mandell et al. (Cancer Research, February 1999, Vol. 59, p. 661-668, IDS of 12/7/2001) in view of Wilson et al. (US Patent 5,652,224) as applied to claims 1-5, 7-9, 11, 13, 15, 17-19, 21, 22, 24, 26, 28, 30, and 31 and further in view of Hidaka et al. (Thyroid, 1996, Vol. 6, p. 23-28) **is maintained.**

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the rationale underlying the present rejection employs hindsight reasoning and that even if the deficiencies of the previously discussed two references were overlooked, further application of reference by Hidaka fails to establish *prima facie* cases of obviousness. In response to Applicants' arguments, the rejection of claim 1, from which the present claims depend, is maintained as discussed above. With regard to the teaching of Hidaka, one would have been motivated to express Hidaka's peroxidase gene in Mandells' and Wilsons' adenoviral vectors comprising an iodine transporter because Hidaka's peroxidase gene and its function has

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been known in the art at the time of the present invention. Thus all claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods (taught by Mandell and Wilson) with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. For the reasons discussed above the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 8-5-2007
Primary Examiner, TC1600